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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,135	05/06/2005	Geoffrey Philip Symonds	J&J2174USNP	2095

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,135	SYMONDS ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *66-130* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Symonds et al.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 66-81, drawn to a method for producing a cytotoxic T-lymphocyte population primed for virus-specific CTL activity comprising a step of preparing non-naturally occurring antigen-presenting cells (nnAPC) which present at least one virus-specific antigen.

Group II, claim(s) 82-94, and 97-99, drawn to a method for producing a cytotoxic T-lymphocyte population transduced with virus-inhibiting nucleic acid and primed for virus specific CTL activity, wherein CD4+ T lymphocytes comprising virus inhibiting nucleic acid are also introduced into the subject.

Group III, claim(s) 82-93, 95 and 97-99, drawn to a method for producing a cytotoxic T-lymphocyte population transduced with virus-inhibiting nucleic acid and primed for virus specific CTL activity, wherein CD34+ hematopoietic progenitor cells comprising virus inhibiting nucleic acid are also introduced into the subject.

Group IV, claim(s) 82-93, and 96-99, drawn to a method for producing a cytotoxic T-lymphocyte population transduced with virus-inhibiting nucleic acid and primed for virus specific CTL activity, wherein both CD34+ hematopoietic progenitor cells comprising virus inhibiting nucleic acid and CD4+ T lymphocytes comprising virus inhibiting nucleic acid are also introduced into the subject.

Group V, claim(s) 100, drawn to a therapeutic cell product comprising a cytotoxic T-lymphocyte population primed for virus-specific CTL activity produced according to the method of claim 66.

Group VI, claim(s) 101, drawn to a therapeutic cell product comprising a cytotoxic T-lymphocyte population transduced with virus-inhibiting nucleic acid and primed for virus-specific CTL activity produced according to the method of claim 82.

Group VII, claim(s) 102-120, and 125-130, drawn to a method of treating a subject with an infectious disease, wherein CD4+ T lymphocytes are also introduced into the subject.

Group VIII, claim(s) 102-117, 121-123 and 125-130, drawn to a method of treating a subject with an infectious disease, wherein CD34+ T lymphocytes are also introduced into the subject.

Group IX, claim(s) 102-117, 124, and 125-130, drawn to a method of treating a subject with an infectious disease, wherein both CD34+ and CD4+ T-lymphocytes are also introduced into the subject.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature linking the Groups I-III appears to be a therapeutic cell product comprising a cytotoxic T-lymphocyte population primed for virus-specific CTL activity produced according to the method of claim 66 (see claim 100). The cytotoxic T-lymphocyte population primed for virus-specific CTL activity produced according to the method of claim 66 cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. WO 02/065992 (Pub. Date 8/29/2002, earliest effective filing date at least 2/19/2002, IDS) teaches a therapeutic T-lymphocyte population primed for the cancer associated peptide which was prepared by the method comprising: a) preparing a non-naturally occurring antigen-presenting cell line (nnAPC), wherein said nnAPC is capable of presenting up to about 15 different peptide molecules that is associated with

cancer; b) harvesting CD8+ cells from said subject; c) stimulating CD8+ cells with said nnAPC cell line; d) adding said CD8+ cells to media that contains a cytokines such as IL-2, IL7, or IL-2 and IL-7 in combination (see page 5), wherein the CD8+ cells are isolated from leukapheresis sample by positive selection using the Dynabeads isolation procedure (see page 34, lines 11-12). While 02/065992 does not teach T-lymphocytes primed for virus-specific antigen, these deficiencies are made up for in the teachings of WO 01/94944A2 (Pub. Date: 12/13/2001, earliest effective filing date: at least 6/1/2001). WO 01/94944A2 teaches nnAPC engineered to express a flu viral peptide and the use of such nnAPCs to prime cytotoxic T lymphocytes (see Example 9). Therefore, it would have been *prima facie* obvious and one skilled in the art would have been motivated to modify the method of WO 02/065992 to prime T-cells with viral specific antigen for treating virus infection in view of the teachings of WO 01/94944A2. Claim 100 therefore lacks inventive steps over WO 02/065,992 in view of WO 01/94944A2. As such, the technical feature linking the inventions is not novel and does not provide contribution over the prior art. Therefore, unity of invention is lacking and the inventions are deemed to be separate.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a): transdominant proteins, intracellular antibodies, antisense molecules, RNA decoys, interfering RNAs, aptamers and ribozymes.

b): Human papilloma virus, Cytomegalovirus, Epstein Barr Virus, Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis D, Hepatitis E, Measles, Mumps, Polio, Rubella, Influenza, Yellow Fever, Japanese Encephalitis, Dengue, Rabies, Rotavirus, Varicella Zoster, Chikungunya Rift Valley Fever, Respiratory Syncitial Virus, Herpes Simplex, Coronaviruses, Marburg, Ebola, California Encephalitis Virus, JC Virus, Lymphocytic Choriomeningitis Virus, Parvovirus, Rhinovirus, Smallpox, HTLV-1, HTLV-2, and HIV.

c): cytotoxic T cell activity, CTL cell purity, sterility and endotoxin content.

d): IL-2, IL-4, IL-7, IL-15, IL-21, IL-2+IL-7.

Applicant is required, in reply to this action, to elect a single species from each of the groups a)-d) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

group a): claims 70, 71, 84 and 107-108

group b): claims 72, 73, 85 and 109-110

group c): claims 78, 92 and 117

group d): claim 79, 82-99, 125 and 126.

The following claim(s) are generic: 66-69, 74-77, 80-81, 100-106, 111-116, 118-124 and 127-130.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons set forth above (see paragraph 2 above).

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.
Art Unit 1643
April 10, 2007

CHRISTOPHER H. YAEN
PRIMARY EXAMINER